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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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BRADLEY N. RUBEN
463 FIRST ST., SUITE 5A
HOBOKEN, NJ 07030-1859

EXAMINER

KIM, VICKIE Y

ART UNIT PAPER NUMBER

1614

DATE MAILED: 01/03/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/576,597

Applicant(s)

VOORHEES ET AL.

Examiner

Vickie Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-50 is/are pending in the application.
- 4a) Of the above claim(s) 33-36, 40-43 and 49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 22-32, 37-39, 44-48 and 50 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 18.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION***Election acknowledged***

Applicant's election with traverse of species (genistein elected) and compound (retinoid elected) in Paper No. 17 is acknowledged. The traversal is on the ground(s) that genistein and quercetin is structurally related and sufficiently small group. This argument seems to be persuasive and this examiner will be accepting applicant's traversal. Therefore, both genistein and quercetin will be included in the examination. It is noted applicant traversal clearly admits that the species to be obvious variants (because their structures are closely related) on the record that this is the case. In any event, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant did not traverse the election requirement on compound (retinoid elected). Therefore, the election requirement on the secondary active compounds is deemed to be proper and made Final.

Status of application

1. Claims 22-50 are pending. Non-elected claims 33-36, 40-43, 49 are withdrawn from the consideration.

Claim Objections

2. The numbering of claims is not in accordance with 37 CFR 1.126 where the claim 43 has numbered twice. When new claims are presented, they must be numbered

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consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Duplicated claim number 43 has been renumbered 44, and following claim numbers 44-49 are also renumbered 45-50 accordingly.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 22-23, 25-28, 45-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Kelly et al (WO 98/08503).

Kelly et al teach a therapeutic method of treating acne using a composition comprising genistein as an active agent, see example 7 at page 34. In the patent(WO'503), claim 1 includes acne treatment and claim 2(3) teaches specifically about genistein as an effective compound.

As to the claims 25-28, the recited routes of administration(i.e. topical and oral delivery) are also taught by the cited reference, see page 10(lines 5-15), and claims 16-17.

As to the claims 45-48, the recited method of ameliorating the symptoms of acne is also taught by the cited reference, see page 8, lines 10-15. Thus all the claimed subject matter is anticipated by the cited reference.

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5. Claims 22, 24 and 45 are rejected under 35 U.S.C. 102(b) as being Yamada et al(JP 59-044313 abstract only).

JP'313 teaches an antibacterial composition useful for treating acne containing quercetin as an active component, see abstract. Thus, the claimed subject matter is taught and anticipated by the cited reference.

6. Claims 22, 24-25, 29, 38-39, 44, 45-48, and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Burger et al(US 5,665,367).

Burger teaches a synergistic skin care composition containing quercetin and a retinoid for treating acne, improving skin condition and quality of skin, see abstract; column 1, line, 18 and column 2, lines 20-35. The limitation recited in claims 45-48 (i.e. ameliorating acne symptoms) is envisaged from the teaching of conditioning skin including increasing general quality of skin condition(i.e controlling sebum excretion, age spots, wrinkles, skin lightening, dry skin, controlling flexibility of skin, etc). In the cited patent, Burger also teaches the flavonoids including narigenin and quercetin is effective in acne treatment in addition to the enhanced effect from the synergistic composition, see column 1-2, wherein the effective treatment from application of flavonoids including quercetin is also envisaged so that the claim 22 and 24 are properly included in this rejection. The synergistic combination of quercetin and retinoid(i.e. retinol) is applied topically to skin for treating acne effectively, see columns 2-3. Thus, all the claimed subject matter is taught and anticipated by the cited reference.

Claim Rejections - 35 USC § 103

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7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 30, 31, 32, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burger et al(US'367) in view of Kelly et al(WO'503).

As mentioned immediately above in 102 rejection(supra), Burger et al teach the effective acne treatment by applying topical synergistic combination of quercetin and retinoid(i.e. retinol). In addition to that, Burger teaches about flavonoids that includes not only quercetin and narigenin but also isoflavones which are acting as potent antioxidants, and inhibiting free radical formation and also acting as an free radical scavengers so that they are effectively used in acne treatment, see column 1, lines 45 – column 2, lines 15.

Applicant's claims 31-32, and 37 differ because it was silent about the specific species of the flavonoid, that is genistein, as an essential component of the said synergistic combination with retinoid.

However, it would have been obvious to substitute genistein to quercetin when Burger et al is taken in view of Kelly et al because Kelly et al teach genistein is an effective species of isoflavones(flavonoids) with anti-acne-activity (as also mentioned in 102 rejection(supra)).

One would have motivated to choose genistein to make a synergistic combination with retinoids to enhance its anti-acne effect because genistein is also well

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known in the art as safe and effective flavonoid used in oral and topical application for the acne treatment.

One would have been motivated to extend Burger's teaching(column 2, lines 3-54) to include various flavonoids having anti-acne activity because it is always desired to increase therapeutic modality to fit patient's need and preference. As applicant admitted in his traversal, these compounds are related and one would have motivated to make this said substitution , with reasonable expectation of success, because genistein and quercetin share similar structures (both are belong to class of flavonoids). Also, these are considered to be obvious variants admitted by applicant in his traversal.

As to applicant's claim 30 that requires oral application, the minor variations including the selection of optimal dosages, routes of administration in order to determine the most effective treatment is well within the skilled level of artisan having ordinary skill in the art, and is obvious. Thus, it is properly included in this rejection.

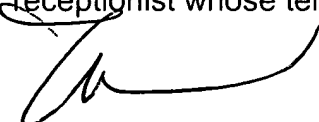
One would have been motivated to combine these references and make the modification because they are drawn to the same technical fields (constituted with same (or similar) ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

Conclusion

9. All the elected claims 22-32, 37-39, 44-48, and 50 are rejected.
10. Non-elected claims 33-36, 40-43, 49 are withdrawn from the consideration.
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675.

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The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Vickie Kim,
Patent examiner
December 11, 2002
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